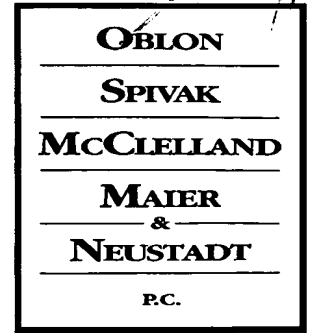




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ATTORNEYS AT LAW

NORMAN F. OBLON
(703) 413-3000
NOBLON@OBLON.COM

ROLAND E. MARTIN
(703) 412-6243
RMARTIN@OBLON.COM
*BAR OTHER THAN VIRGINIA

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

RE: Application Serial No.: 09/913,721
Applicants: Yoshio HIRAKI et al
Filing Date: August 17, 2001
For: SKIN PREPARATIONS FOR EXTERNAL USE
Group Art Unit: 1617
Examiner: Gina YU

SIR:

Attached hereto for filing are the following papers:

**APPEAL BRIEF W/ATTACHED APPENDIX
(IN TRIPLICATE)**

Our credit card payment form in the amount of **\$330.00** is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.


Norman F. Oblon

Registration No. 24,618

Customer Number

22850

(703) 413-3000 (phone)
(703) 413-2220 (fax)

Roland E. Martin
Registration No. 48,082

10/31/2003 EFLORES 00000152 09913721

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1940 DUKE STREET ALEXANDRIA, VIRGINIA 22314 U.S.A.
TELEPHONE: 703-413-3000 FACSIMILE: 703-413-2220 WWW.OBLON.COM

DOCKET NO: 211463US0PCT



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF :
Yoshio HIRAKI et al : GROUP ART UNIT: 1617
SERIAL NO.: 09/913,721 : EXAMINER: Gina YU
FILED: August 17, 2001 :
FOR: SKIN PREPARATIONS FOR EXTERNAL USE

APPEAL BRIEF

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Appellants' appeal the final rejection of Claims 1-13 of the above-identified application, as set forth in the final Official Action dated May 7, 2003.

I. REAL PARTY IN INTEREST

The real party in interest is Kabushiki Kaisha Yakult Honsha by virtue of the assignment executed on June 14, 2001. The executed assignment was forwarded to the U.S. Patent and Trademark Office and recorded on November 19, 2001.

II. RELATED APPEALS AND INTERFERENCES

To the best of Appellants' undersigned representative's knowledge, there are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-13 are the only claims pending in the above-identified application. Claims 1-13 are appealed.

IV. STATUS OF AMENDMENTS

An amendment was submitted in response to a Final Rejection mailed May 7, 2003. The amendment was filed July 8, 2003, amending Claims 1-13. The amendment was entered in the Advisory Action mailed August 13, 2003.

V. SUMMARY OF INVENTION

The present invention relates to a skin preparation for external use which has an lamellar structure containing one or more fatty acid monoglyceride(s) and one or more of vitamin A and vitamin A precursor(s), derivative(s) and decomposed product(s) thereof. The skin preparation may further contain cholesterol and the lamellar structure may be a multi-lamellar vesicle. See page 1, lines 6 and 7; page 3, line 25 through page 4, line 1; page 4, lines 11-16; and page 5, lines 23-27 of the specification.

VI. ISSUES

The issues in this appeal are as follows: whether or not Claims 1-9 and 11-13 are unpatentable under 35 U.S.C. §103(a) over Mathur et al (U.S. 5,260,065) and whether Claim 10 is unpatentable under 35 U.S.C. §103(a) over Mathur et al (U.S. 5,260,065) in view of Yiournas et al (U.S. 5,013,497).

The rejection of Claims 1-13 under 35 U.S.C. §112, second paragraph, was deleted in the Advisory Action mailed August 13, 2003.

VII. GROUPING OF CLAIMS

Claims 1-9 and 11-13 stand or fall together. The patentability of Claim 10 will be argued in a separate paragraph below.

VIII. ARGUMENTS AGAINST THE REJECTION OF CLAIMS 1-9 AND 11-13

UNDER 35 U.S.C. §103 OVER MATHUR ET AL

Claims 1-9 and 11-13 recite a skin preparation comprising a lamellar structure consisting essentially of one or more fatty acid monoglyceride(s), and one or more of vitamin A and vitamin A precursor(s), and derivative(s) and decomposed product(s) thereof.

Mathur et al disclose blended lipid vesicles which must contain a primary lipid, disclosed in column 2 of Mathur et al to include fatty acid monoglycerides and a secondary lipid different from the primary lipid and also disclosed in column 2 of Mathur et al. The composition for forming the lipid vesicles may further include cholesterol, but must include both the primary and secondary lipids (see column 3, line 66 through column 4, line 14 of Mathur et al.). Mathur et al further disclose the addition of retinoic acid with the blended lipid vesicles in Table 2 and Table 5 of the reference.

In column 4, the reference states that “in certain circumstances, cholesterol will allow these materials which will not otherwise form a lamellar phase to form a lamellar phase, but they cannot be formed into the vesicles without the addition of a secondary lipid”. Therefore, it is clear that Mathur et al teaches away from a skin preparation having a lamellar structure having one or more fatty acid monoglyceride(s) and one or more of vitamin A, and vitamin A precursor(s), derivative(s), and decomposed product(s) thereof. The so-called lamellar phase discussed in column 4 of the reference is never used for carrying a material to form a skin preparation composition and does not have a lamellar structure capable of carrying vitamin

A, and vitamin A precursor(s), derivative(s) and decomposed product(s) thereof, but must be further formed into vesicles by the addition of a secondary lipid. The secondary lipid is excluded from the claims by the recitation of a term “consisting essentially of”, since the addition of a secondary lipid would change the essential nature of the composition of the present claims.

The Examiner asserts that, since there is not a clear indication in the specification or claims, of what the basic novel characteristics of the invention are, the phrase “consisting essentially of” will be construed as “comprising”. The basic and novel characteristics of the invention are set forth on page 4, line 11 through page 5, line 2, which clearly sets forth the fact that a lamellar structure may be formed using only a fatty acid monoglyceride without the addition of a secondary lipid, such as that disclosed in Mathur et al, and with an optional sterol additive, i.e., cholesterol, which is added only for the purpose of improving the stability of the lamellar structure, and not for the purpose of forming the lamellar structure itself. Since Mathur et al indicate in column 4 only a lamellar phase may be formed by the use of an additive like cholesterol, which is not used by Mathur et al to carry cosmetic or pharmaceutical compositions, but not a lamellar structure, for example, a vesicle, as in the present claims, which is useful for carrying the above compositions, and that a lamellar structure, for example, a vesicle, cannot be formed without the addition of the secondary lipid, it is clear that the term “consisting essentially of” excludes secondary lipids, which would change the essential nature of the composition, but not a sterol additive, i.e., cholesterol, which is only useful in improving the stability of a lamellar structure and not necessary for the formation of a lamellar structure. The claims distinguish over the combination of references.

Arguments against the rejection of Claim 10 under 35 U.S.C. § 103(a) over Mathur et al in view of Yiournas et al.

In addition to the arguments for patentability of Claims 1-9 and 11-13 in the paragraph above, Yiournas et al does not remedy the deficiencies of Mathur et al since Yiournas et al is directed only to the disclosure that multi-lamellar vesicles are said to be “best for encapsulation in transportation of lipophilic materials” and does not teach or suggest a skin preparation having a lamellar structure consisting essentially of one or more fatty acid monoglyceride(s), and one or more of vitamin A and vitamin A precursor(s), derivative(s) and decomposed product(s), as in the present claims. Claim 10 distinguishes over the combination of references.

In view of the preceding arguments, Appellants respectfully request that the Examiner’s rejection of Claims 1-13 be reversed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

Customer Number

22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/03)
NFO/REM/cja



Norman F. Oblon
Attorney of Record
Registration No. 24,618

Roland Martin
Registration No. 48,082

APPENDIX

Pending claims in Application Serial No. 09/913,721

Claim 1. A skin preparation comprising a lamellar structure consisting essentially of one or more fatty acid monoglyceride(s), and one or more of vitamin A and vitamin A precursor(s), derivative(s) and decomposed product(s) thereof.

Claim 2. The skin preparation according to Claim 1, which comprises a lamellar structure prepared from an oil phase mixture containing said one or more fatty acid monoglyceride(s) and said one or more of vitamin A and vitamin A precursor(s), derivative(s) and decomposed product(s) thereof.

Claim 3. The skin preparation according to Claim 1, wherein said one or more of vitamin A and vitamin A precursor(s), derivative(s) and decomposed product(s) thereof is contained within or covered with the lamellar structure composed mainly of said one or more fatty acid monoglyceride(s).

Claim 4. The skin preparation according to Claim 1, wherein the amounts of said one or more fatty acid monoglyceride(s) and said one or more vitamin A and vitamin A precursor(s), derivative(s) and decomposed product(s) thereof is 2 to 100 parts by weight of said one or more fatty acid monoglyceride(s) per part by weight of said one or more vitamin A precursor(s), derivative(s) and decomposed product(s) thereof.

Claim 5. The skin preparation according to any one of the Claims 1 to 4, comprising a cosmetic composition.

Claim 6. The skin preparation according to Claim 5, wherein said cosmetic composition is selected from the group consisting of a cosmetic lotion, a cosmetic milk, a cosmetic cream, a beauty essence, a face washing cream, a pack, a cleansing cream and a massaging cream.

Claim 7. The skin preparation according to Claim 1, wherein the amounts of said one or more fatty acid monoglyceride(s) and said one or more vitamin A and vitamin A precursor(s), derivative(s) and decomposed product(s) thereof is 5 to 50 parts by weight of said one or more fatty acid monoglyceride(s) per part by weight of said one or more vitamin A precursor(s), derivative(s) and decomposed product(s) thereof.

Claim 8. The skin preparation according to Claim 1, wherein the content of said one or more fatty acid monoglyceride(s) is 0.1 to 25% by weight and the content of said one or more vitamin A and vitamin A precursor(s), derivative(s) and decomposed product(s) thereof is 0.001 to 2% by weight.

Claim 9. The skin preparation according to Claim 1, wherein the content of said one or more fatty acid monoglyceride(s) is 0.5 to 10% by weight and the content of said one or more vitamin A and vitamin A precursor(s), derivative(s) and decomposed product(s) thereof is 0.01 to 0.3% by weight.

Claim 10. The skin preparation according to Claim 1, wherein said lamellar structure is a multi-lamellar vesicle.

Claim 11. The skin preparation according to Claim 1, further comprising cholesterol in an amount range of 0.01 to 1 per part by weight of said one or more fatty acid monoglyceride(s).

Claim 12. The skin preparation according to Claim 1, wherein said one or more fatty acid monoglyceride(s) are monoglyceride(s) of saturated or unsaturated fatty acids having 8 to 18 carbon atoms.

Claim 13. The skin preparation according to Claim 1, wherein said one or more fatty acid monoglyceride(s) are selected from the group consisting of myristic acid monoglyceride, palmitic acid monoglyceride and stearic acid monoglyceride.